K111525 510(K) SUMMARY

AUG 2 4 2011

MEDTRONIC Sofamor Danek
PERIMETER® Interbody Fusion Device
August 2011

I. **Company:**

Medtronic Sofamor Danek, Inc.
1800 Pyramid Place
Memphis, Tennessee 38132
(901) 396-3133

Contact:

Michael Scott
Sr. Regulatory Affairs Specialist

II.

Product Name:	PERIMETER® Interbody Fusion Device
Common Name:	Interbody Fusion Device
Classification Name:	Intervertebral Body Fusion Device
Classification Panel:	Class II (special controls)
Regulation:	21 CFR 888.3080
Product Code(s)	MAX

III. **Description**: The PERIMETER® Interbody Fusion Device consists of cages of various widths and heights which can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with autogenous bone graft. The PERIMETER® Interbody Device is to be used with supplemental instrumentation.

The device is offered in Titanium Alloy (Titanium-6Aluminum-4Vanadium ELI) or PEEK Optima LT1 (Polyetheretherketone). This interbody device is provided in sterile or non-sterile forms. Refer to the package label for specific implant sterility information.

The PERIMETER® Interbody Fusion Device is offered in a variety of sizes ranging from 8mm to 20mm in height, 21mm to 28mm in length and between 19mm and 38mm in width. An array of lordosis options are provided for this device spanning from 4 degrees to 15 degrees of angulation. Both the PEEK Optima LT1 and Titanium Alloy devices are designed with teeth across both the superior and inferior surfaces to allow the implant to grip the superior and inferior end plates, thus providing expulsion resistance. Additionally, the Titanium Alloy version of this device offers lateral windows for visibility of the Autogenous bone graft.

Based on fatigue testing results, when using the PERIMETER Interbody Fusion Device, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of this system.

Never use stainless steel and titanium implant components in the same construct.

Medical grade titanium, titanium alloy, and/or medical grade cobalt-chromium-molybdenum alloy may be used together. Never use titanium, titanium alloy, and/or medical grade cobalt-chromium-molybdenum alloy with stainless steel in the same construct. PEEK Optima-LT1 implants may be used with stainless steel, titanium, or cobalt-chromium-molybdenum alloy implants.

Indications for Use:

The PERIMETER® Interbody Fusion Device is indicated for interbody fusion with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

These implants may be implanted via a variety of open or minimally invasive approaches. These approaches include anterior, lateral and oblique. These devices are intended to be used with supplemental fixation instrumentation, which has been cleared for use in the lumbar spine.

Substantial Equivalence:

The subject PERIMETER® Interbody Fusion Device System is substantially equivalent to the predicate PERIMETER® Interbody Fusion Device (K090353 (S.E. 09/29/2009)) in terms of fundamental technology, intended use, indications for use and intervertebral body design and fundamental scientific technology.

IV. **Technological Characteristics:**

The purpose of this 510(k) is to include additional titanium versions of the PERIMETER® Interbody Fusion Device System. A revised surgical technique and IFU with the updated information to include the titanium version has also been included in this 510(k) submission.

The subject and predicate PERIMETER® Interbody Fusion Device are identical in terms of indications for use, intended use and performance specifications.

SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE*		
Performance Test Summary-New Device		
Characteristic	Standard/Test/FDA Guidance	Results Summary
Dynamic Axial Compression Bending Static Compression Bending Static Compression Shear	ASTM 2077-03 "Test Methods for Intervertebral Body Fusion Devices" An Finite Element Analysis in line with ASTM 2077-03 was used to assess Static Compression Bending and Static Compression Shear	The subject device successfully met all acceptance criteria for these tests. Additional documentation was provided which demonstrated the subject intervertebral devices to be substantially equivalent to the predicate PERIMETER® Interbody Fusion Device

Conclusions Drawn from the Non-Clinical Tests

The subject PERIMETER® Interbody Fusion Device System is substantially equivalent to the predicate PERIMETER® Interbody Fusion Device (K090353 (S.E. 09/29/2009)) in terms of fundamental technology, intended use, indications for use and intervertebral body design and fundamental scientific technology.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG 24 2011

Medtronic Sofamor Danek, Inc.
% Mr. Michael Scott
Sr. Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K111525
Trade/Device Name: PERIMETER® Interbody Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: July 22, 2011
Received: July 25, 2011

Dear Mr. Scott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

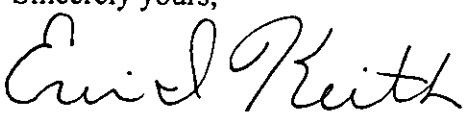
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K111525

Device Name: PERIMETER® Interbody Fusion Device

Indications for Use:

The PERIMETER® Interbody Fusion Device is indicated for interbody fusion with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via a variety of open or minimally invasive approaches. These approaches include anterior, lateral and oblique. These devices are intended to be used with supplemental fixation instrumentation, which has been cleared for use in the lumbar spine.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
Per 21 CFR 801.109

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111525